DEPARTMENT OF PHARMACY
GURU GHASIDAS VISHWAVIDYALAYA (A CENTRAL UNIVERSITY)
BILASPUR (C.G.)

Pre Ph.D. Course Work in Pharmacy

Scheme of Examination

Subject Code	Subjects	Contact hours/		Maximum Marks	Total Marks
		Theory	Tutorials		
PY-PH-1	Paper-I Research Methodology	4	2	100	100
PY-PH-2	Paper-II Modern Analytical Techniques	4	2	100	100
PY-PH-3	Paper-III Elective [Any one paper to be chosen by the candidate] Pharmaceutics OR Pharmaceutical Chemistry OR Pharmacology OR Pharmacognosy	4	2	100	100

SEMINAR: For being qualified in seminar the average marks given by different members of the panel of examiners should not be below 50%. The evaluation process will be as follows-

1	Subject Content	-	40
2	Presentation Skills	-	20
3	Justification & Scope of the Work	-	10
4	Ability to answer question asked	-	20
5	Resources used (Bibliographical references)	-	10
	Total	**-**	**100**

Note: Candidates securing 50% or above will be qualified in seminar.

Pre Ph.D. Course Work

Programme Outcomes

Ph.D. students will be able to know about:

PO1: Basics on research methodology and its techniques: Definition and applications of research, research process and steps, importance of literatures and review process, research design, strategies and basic principles of experiments, statistical concept, research proposal, writing a research report, research content, intellectual property rights, computational analysis and its applications, statistical data analysis etc.

PO2: Advancement in Modern Analytical Techniques: Principles and methods of analytical technique, interpretation of data, chromatographic techniques, spectroscopic techniques, thermal analytical techniques, assaying of drugs and metabolites, bioassays and applications.

PO3: Advancement in Pharmaceutics: Basics of pharmacokinetics and pharmacodynamic, formulation development, drug targeting to particular organs, designing and evaluations of controlled release systems, chronotropic drug delivery systems, kinetics and drug stability, stability testing methods, testing as per ICH guidelines, shelf life determinations.

PO4: Advancement in Pharmaceutical Chemistry: Molecular modelling in drug design, energy minimization technique, analog design, quantitative structure activity relashioship (QSAR), pharmacophore mapping, structure based drug design, software aided drug design, peptides and peptidomimetics, docking and scoring functions, de novo drug design, natural product leads for new pharmaceuticals, synthesis and mode of action of various class of drugs.

PO5: Advances in Pharmacology: Principles of pharmacological and clinical emulation of drugs, standard techniques used in laboratory animals, CPCSEA guidelines, principles of toxicology, safety evaluations of new drugs in animals, ICH & OECD guidelines, molecular mechanisms of drug action, theory of receptor occupancy and cellular signalling system, intracellular receptors, endogenous bioactive molecules and different classes of receptors, introduction to clinical trials, clinical research, phases of clinical trials, role of regulatory in clinical research and new drug development.

PO6: Advances in Pharmacognosy: Identification of medicinal plants, collection and preparation of medicinal plants for pharmacognostic research, preparation of herbarium specimen, general methods of extraction, isolation and purification of alkaloids, glycosides and tannins, bioactivity guided drug discovery, structure elucidation of plant constituents, standardization of phytopharmaceuticals, WHO guidelines for standardization, quality control of herbal drugs, evaluation of biological activity of crude drugs extracts, pharmacological activities studies for phytopharmaceticals.

Programme Specific Outcomes:

PSO1: The advanced research methodology impart knowledge on the area of research design, strategies and basic principles of experiments, statistical concept, research process and steps, importance of literatures review process. It also helps our students to impart advanced knowledge and skills in connection to intellectual property rights, computational analysis and its applications, statistical data analysis.

PSO2: Impart advanced knowledge and skills regarding interpretation of data, methods of analytical technique, chromatographic techniques and spectroscopic techniques, thermal analytical techniques, assaying of drugs and metabolites, bioassays and applications etc.

PSO3: Impart advanced knowledge about pharmaceutics (CDDS, Drug targeting, Chronotropic Systems, kinetics and drug stability), **Pharmaceutical Chemistry (**drug design, QSAR, natural product as leads for new pharmaceuticals, synthesis, mode of action, uses of various classes of drugs), **Pharmacology (**pharmacological and clinical emulation of drugs, CPCSEA guidelines, ICH & OECD guidelines, molecular mechanisms of drug action, introduction to clinical trials, clinical research**) and Pharmacognosy (**medicinal plants, extraction, isolation and purification of alkaloids, glycosides and tannins, bioactivity guided drug discovery, structure elucidation of plant constituents, WHO guidelines for standardization, quality control of herbal drugs**).**

Paper-I
Research Methodology (PY-PH-1)

UNIT 1: RESEARCH

1. Definition of research, application of research and types, research and types, research process and steps.
2. Literature review: importance of literature review, method and sources of literature review, review the literature selected, development of a theoretical and conceptual framework, writing up the review.

UNIT 2: RESEARCH DESIGN

Design of experiments – objectives, strategies and basic principles; simple comparative experiments- basic statistical concept, sample mean and variance, random variable, standard normal distribution, statistical hypothesis degree of freedom, two sample t-test, F-test, Chi-square test, P-value, Confidence Intervals, Paired t-test; Analysis of Variance (ANOVA) for fixed effect model, ANOVA for randomized complete block design to control effects of nuisance factor; correlation regression.

UNIT 3: RESEARCH PROPOSAL

1. Content – Preamble, problem, objective, hypothesis, design of study, measurement procedure, analysis of data, organization of report, displaying data tables, graphs and charts.
2. Writing a research paper report- development an outline; Key elements- objectives, introduction, design of work, experiment methods, procedure, measurements, result, discussion, conclusion, referencing and the various formats for reference. Report writing- Prewriting considerations, thesis writing, formats of report writing, formats of publications in scientific journals.

UNIT 4: INTELLECTUAL PROPERTY RIGHTS

Indian Patent Act 1970 & its latest amendments; intellectual property right- concepts, copyright, design. Trademark, trademark, application, processing of patent. Patent term extension, criteria for granting patents; patent writing.

UNIT 5: COMPUTATIONAL ANALYSIS

1. Introduction to the creation and advancement of database, algorithms, computational and statistical technique for data analysis.
2. Application of Microsoft excel for quantitative and statistical data analysis, power point, introduction to internet database surfing.

Course Outcome:

Upon completion of this course it is expected that scholars will be able know

CO1. About Research process and steps, literature review, development of theoretical and conceptual framework.

CO2. Research design and basic statistical concepts.

CO3. Intellectual Property Rights (IPR).

CO4. Computational analysis and its applications

Course Outcomes and their mapping with Programme Outcomes:

CO	PO						PSO		
	PO1	PO2	PO3	PO4	PO5	PO6	PSO1	PSO2	PSO3
CO1	3		1	1	1	1	3	3	2
CO2	3	1	1	1	1	1	3	3	3
CO3	3						3		
CO4	3	1					3		

Weightage: 1-Sightly; 2-Moderately; 3-Strongly

Paper-II
Modern Analytical Techniques (PY-PH-2)

UNIT 1: Principles, methods, interpretation of data and application of chromatographic techniques: TLC, Gc, HPLC, Ion chromatography, Gel electrophoresis.

UNIT 2: Principles, methods, interpretation of data and application of spectroscopic techniques: UV-Visible, IR, NMR, Mass, Fluorimetry and AAS.

UNIT 3: Principles, methods, interpretation of data and application of LC-MS, GC-MS, Thermal methods (TGA, DTA & DSC), XRD, SEM and TEM.

UNIT 4: Assay of drugs and metabolites in biological fluids.

UNIT 5: Bioassay, various types of bioassays, advantages and limitations of bioassay with suitable examples, radioimmunoassay, ELISA and their applications in medicine.

Course Outcome:

At the end of this course, students will able to know,

CO1. Interpretation of data and methods of analytical technique.

CO2. Chromatographic techniques and spectroscopic techniques.

CO3. Thermal analytical techniques and assaying of drugs and metabolites.

CO4. Bioassays and its application.

Course Outcomes and their mapping with Programme Outcomes:

CO	PO						PSO		
	PO1	PO2	PO3	PO4	PO5	PO6	PSO1	PSO2	PSO3
CO1	1	3	1	1	1	1		3	1

CO2	1	3	1	1	1	1		3	1
CO3		3						3	1
CO4	1	3						3	1

Weightage: 1-Sightly; 2-Moderately; 3-Strongly

Paper-III
Optional Paper: Pharmaceutics (PY-PH-3)

UNIT 1: Pharmacokinetic and Pharmacodynamic basis of controlled drug delivery.

Formulation development of:

a) Controlled release oral drug delivery systems

b) Parenteral controlled release drug delivery systems

c) Chemically modified drug delivery system

UNIT 2: Drug targeting to particular organs:

a) Problems of drug delivery to the brain and targeting to brain

b) Drug targeting in neoplastic diseases

c) Drug targeting to gastro-intestinal tract

UNIT 3: Design, fabrication, evaluation and applications of the following controlled release systems:

a) Micro particulate drug carriers: Microspheres, Nanoparticles

b) Vesicular carriers: Liposomes, Niosomes, Transfersomes, Ethosomes

c) Cellular carriers: Resealed erythrocytes.

UNIT 4: Chronotropic drug delivery systems

Designing of Chronotropic Systems: Multi-Layered tablets and capsules, Press coated tablets, Core-cup-tablets, Multiparticulate systems, Pulsincap systems, Chrono- modulating microchips.

UNIT 5: Kinetics and drug stability, Strategy of stability testing, method of stabilization, method of accelerated stability testing in dosage forms as per ICH guidelines, Comparison of stability testing requirements of ICH with other international regulatory agencies, Determination of shelf life.

Course Outcome:

At the end of this course, students will able to know,

CO1. Basics of pharmacokinetics and pharmacodynamic.

CO2. Formulation development, drug targeting to particular organs.

CO3. Designing and evaluations of controlled release systems, Chronotropic Systems.

CO4. Kinetics and drug stability, stability testing methods, testing as per ICH guidelines, shelf life determinations.

Course Outcomes and their mapping with Programme Outcomes:

CO	PO						PSO		
	PO1	PO2	PO3	PO4	PO5	PO6	PSO1	PSO2	PSO3
CO1	1		3						2
CO2	1		3						2
CO3		1	3				1		2
CO4	1	1	3						2

Weightage: 1-Sightly; 2-Moderately; 3-Strongly

Paper-III
Optional Paper: Pharmaceutical Chemistry (PY-PH-3)

UNIT 1: Molecular modelling in drug design: Introduction, Molecular mechanics, Quantum mechanics, Molecular dynamics, Energy minimization techniques, Conformational search, Known and Unknown receptor.

UNIT 2: Analog design; Quantitative structure activity relationship (QSAR): Introduction, Parameters, Quantitative models and applications; 2D QSAR approaches for drug design; Recent trends in QSAR; Pharmacophore mapping.

UNIT 3: Structure based drug design: Introduction, structure aided drug design process, methods to derive three dimensional structure (obtaining the target, crystallography, nuclear magnetic resonance, homologous modelling), the design process, software-aided drug design, optimization of the identified compounds, examples of structure aided drug design. Docking and Scoring functions; *de novo* drug design.

UNIT 4: Peptides and peptidomimetics; Design and application of prodrugs; Drug metabolism and drug design; Natural products as lead for new pharmaceuticals.

UNIT 5: Classification, synthesis mode of action, structure activity relationship and recent advances of following categories of drugs – Antihistamines (H_1, H_2, H_3 & H_4), Antihypertensives, Anxiolytics, Oral hypoglycaemic agents, NSAID's including COX-2 inhibitors, Fluroquinolones as Antibacterial agents, Classical antiviral agents and design of new antiviral agents; Anticancer agents.

Course Outcome:

At the end of this course, students will able to know,

CO1. Drug design, analog design, de novo drug design, structure based drug design, software aided drug design.

CO2. Quantitative structure activity relationship (QSAR).

CO3. Natural products as lead for new pharmaceuticals.

CO4. Synthesis, mode of action, uses of various classes of drugs.

Course Outcomes and their mapping with Programme Outcomes:

CO	PO						PSO		
	PO1	PO2	PO3	PO4	PO5	PO6	PSO1	PSO2	PSO3
CO1	1			3					2
CO2	1			3					2
CO3	1	1		3			1		2
CO4	1	1		3				1	2

Weightage: 1-Sightly; 2-Moderately; 3-Strongly

Paper-III
Optional Paper: Pharmacology (PY-PH-3)

UNIT 1: Principles of Pharmacological and Clinical Evaluation of drugs: Commonly used laboratory animals in pharmacological research. Standard techniques used in laboratory animals, euthanasia of experimental animals, regulations for laboratory animal care as per CPCSEA guidelines.

UNIT 2: Toxicology: Principles of toxicity evaluations: Safety evaluation of new drugs in animals including acute, sub-acute, sub-chronic and chronic toxicity. ED50 and LD50 determination. Various guidelines for toxicity studies like ICH and OECD.

UNIT 3: Molecular mechanism of drug action: Theory of receptor occupancy and cellular signaling systems such as G-proteins, cyclic nucleotides, calcium and phosphatidyl inositol and intracellular receptors.

UNIT 4: Endogenous bioactive molecules and different classes of receptors: such as cytokines, neuropeptides, neurosteroids, nitric oxide and arachidonic acid metabolites. Angiotensin, Glutamate, Adrenergic, Cholinergic, Dopamine, Serotonin, GABA, Opiod and Purinergic receptors.

UNIT 5: Introduction to clinical Trial: Types of clinical research, phases of clinical research, role of clinical trial in new drug developments. IND, NDA, ANDA:- Parts and contents.

Course Outcome:

At the end of this course, students will able to know,

CO1. Principles of pharmacological and clinical emulation of drugs.

CO2. Standard techniques used in laboratory animals, CPCSEA guidelines, principles of toxicology, safety evaluations of new drugs in animals, ICH & OECD guidelines.

CO3. Molecular mechanisms of drug action, theory of receptor occupancy and cellular signalling system, intracellular receptors,.

CO4. Introduction to clinical trials, clinical research, phases of clinical trials, role of regulatory in clinical research and new drug development.

Course Outcomes and their mapping with Programme Outcomes:

CO	PO						PSO		
	PO1	PO2	PO3	PO4	PO5	PO6	PSO1	PSO2	PSO3
CO1	1				3		1		2
CO2	1				3		1		2
CO3	1	1			3		1		2
CO4	1	1			3		1	1	2

Weightage: 1-Sightly; 2-Moderately; 3-Strongly

Paper-III
Optional Paper: Pharmacognosy (PY-PH-3)

UNIT 1: Identification of medicinal plants: Preparation of herbarium specimen and its authentication, Collection and preparation of medicinal plants for pharmacognostic research.

UNIT 2: General methods of extraction, isolation and purification of alkaloids, glycosides and aglycones, tannins, essential oils, fixed oils and fats with special emphasis on bioactivity guided drug discovery.

UNIT 3: Structure elucidation of plant constituents viz. morphine, atropine, quinine, digoxin, diosgenin, glycerrhetinic acid, rutin, podophyllotoxin and menthol.

UNIT 4: Standardization of phytopharmaceuticals and standardized extracts of alkaloids, glycosides and aglycones, tannins, essential oils, fixed oils and fats by modern analytical techniques with special emphasis on HPLC and HPTLC studies; WHO guidelines for standardization and quality control of herbal drugs.

UNIT 5: Evaluation of biological activity of crude drug extracts and pure phytopharmaceuticals for:

a. Analgesic and antipyretic activity
b. Anti-inflammatory and antiarthritic activity
c. Immunomodulatory activity
d. Antidiabetic activity
e. Hepatoprotective activity
f. Antioxidant activity
g. Anticancer activity
h. Antimicrobial activity

Toxicity studies: acute, subacute and chronic.

Course Outcome:

At the end of this course, students will able to know,

CO1. Identification of medicinal plants, collection and preparation of medicinal plants for pharmacognostic research, preparation of herbarium specimen.

CO2. General methods of extraction, isolation and purification of alkaloids, glycosides and tannins, bioactivity guided drug discovery.

CO3. Structure elucidation of plant constituents, standardization of phytopharmaceuticals.

CO4. WHO guidelines for standardization, quality control of herbal drugs, evaluation of biological activity of crude drugs extracts, pharmacological activities studies for phytopharmaceticals.

Course Outcomes and their mapping with Programme Outcomes:

CO	PO						PSO		
	PO1	PO2	PO3	PO4	PO5	PO6	PSO1	PSO2	PSO3
CO1	1					3	1		2
CO2	1					3	1		2
CO3	1	1				3	1		2
CO4	1	1				3	1	1	2

Weightage: 1-Sightly; 2-Moderately; 3-Strongly